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10/607,077	06/25/2003	Matthew Ashby	ASHBY/1 DIV	1068

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EXAMINER	
STRZELECKA, TERESA E	

ART UNIT	PAPER NUMBER
1637	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/607,077	ASHBY, MATTHEW	
	Examiner	Art Unit	
	TERESA E. STRZELECKA	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 September 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *45,47-50 and 58-69* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *45,47-50 and 58-69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This office action is in response to an amendment filed September 8, 2009. Claims 45-50 and 57 were previously pending. Applicant cancelled claims 46 and 57, amended claims 45 and 47-49 and added new claims 58-69. Claims 45, 47-49 and 58-69 are pending and will be examined.

2. Applicant's amendments and the declaration of Dr. Ashby filed December 23, 2008 overcame the rejection of claims 45-50 and 57 under 35 U.S.C. 112, first paragraph, enablement; the rejection of claims 45, 46 and 57 under 35 U.S.C. 102(b) as anticipated by Wikstrom et al. and the rejection of claims 47-49 under 35 U.S.C. 1039a) over Wikstrom et al. and Clarke et al. Applicant's arguments overcame the rejection of claims 45-57 and 57 under 35 U.S.C. 112, first paragraph, best mode and the objection to specification based on the lack of sequence for primer 1392R.

3. This office action contains new grounds for rejection necessitated by amendment.

Claim Interpretation

4. The term "environmental sample" has not been defined by Applicant, therefore it is interpreted as any sample.

5. The term "environmental parameter" has not been defined by Applicant, therefore it is interpreted as any parameter.

6. The term "abundance of gene segments" has not been defined by Applicant, therefore it is interpreted as either presence/absence of gene segments or a number of gene sequences.

7. The term "parameter of interest is surface oil or natural gas deposit" in interpreted as any parameter pertaining to oil or gas.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

9. Claims 45, 47, 58-61, 65 and 67-69 are rejected under 35 U.S.C. 102(a) as being anticipated by Matsuki et al. (Appl. Environ. Microbiol., vol. 65, pp. 4506-4512, October 1999).

Claims 45, 60 and 65 are considered together in claim 45.

Regarding claims 45, 60 and 65 Matsuki et al. teach a culture-independent method of determining the abundance of an environmental parameter in an environmental sample comprising the steps of:

a. providing a first plurality of environmental samples at least some of which samples contain the environmental parameter (Matsuki et al. teach providing bacterial strains containing species of Bifidobacteria (=environmental parameter) (page 4506, last paragraph; Table 1).);

b. isolating a plurality of genomic DNAs from the environmental each of the samples provided in step a (page 4508, fifth paragraph);

c. isolating a plurality of 16S rRNA gene segments from each plurality of genomic DNAs isolated in step b (page 4507, first paragraph; page 4508, fifth paragraph);

d. determining the abundance of each of said 16S rRNA gene segments in each plurality of 16S rRNA gene segments isolated in step c (page 4507, first and second paragraph; Table 3; Fig. 1);

e. determining the abundance of the environmental parameter in each of the samples provided in step a (Table 3, Fig. 1);

f. correlating the abundance of each 16S rRNA gene segment determined in step d with the abundance of the environmental parameter determined in step e (Table 3; Fig. 1; page 4508, last paragraph; page 4509, first paragraph);

g. selecting at least one 16S rRNA gene segment whose abundance correlates to the abundance of said environmental parameter, as determined in step f (page 4508, fifth paragraph, where the segments selected are defined by the primers which amplify them);

h. providing an environmental sample set of at least one environmental sample (page 4507, last paragraph; page 4508, first paragraph);

i. isolating a plurality of genomic DNAs from each environmental sample of the environmental sample set provided in step h (page 4508, second paragraph);

j. determining the abundance of said 16S rRNA gene segment in step g in each plurality of genomic DNAs isolated in step I (page 4508, second paragraph; page 4510, second paragraph; page 4511, first paragraph); and

k. inferring the abundance of the environmental parameter in each environmental sample of the environmental sample set provided in step h based upon the abundance of said 16S rRNA gene determined in step j in each environmental sample of the environmental sample set provided in step h (Table 4-6; page 4511, third paragraph).

Regarding claim 60, Matsuki et al. teach designating the fragments amplified by the PCR primers as indicators of the presence of the bacteria (page 4508, fifth and sixth paragraphs; page 4509, first paragraph; Fig. 1).

Regarding claims 47 and 61, Matsuki et al. teach that if the 16S rRNA segment was amplified, the Bifidobacterium strain was present in the sample (Fig. 1, for example), therefore, there was a 100% correlation between the presence of the PCR amplicon and the presence of the bacteria in a sample, which can be expressed as an r-factor of 1.

Regarding claims 58, 59, 67 and 68, Matsuki et al. teach PCR (page 4507, second paragraph; page 4508, second paragraph). Since PCR relies on hybridization of primers to target sequences, it is also a hybridization method.

Regarding claim 69, Matsuki et al. teach cell cultures (page 4506, last paragraph) and a physiologican condition of a presence of bifidobacteria in an organism (page 4506, second paragraph).

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. Claims 48, 49, 62 and 63 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matsuki et al. (Appl. Environ. Microbiol., vol. 65, pp. 4506-4512, October 1999) and Clarke et al. (J. Nutr., vol. 120, pp. 218-224, 1990; cited in the previous office action).

A) The teachings of Matsuki et al. are described above. They do not teach calculating correlation coefficients to analyze their data. However, it was well known in the art at the time of the invention how to determine a correlation coefficient between two variables, for example, a level of gene expression and level of sugar, as shown by Clarke et al. on page 222, Fig. 4.

Therefore it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to represent the data of Matsuki et al. in a form of correlation coefficients as customary in the art. For example, one could analyze data presented in Tables 4-6, from the pint of view of correlation between the types of bacteria and number of samples, percentage of different types of bacteria in the population, etc.

12. Claims 45, 50, 60 and 64-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Leu et al. (Anaerobe, vol. 4, pp. 165-174, 1998; cited in the previous office action) and Devereux et al. (Appl. Environ. Microbiol., vol. 60, pp. 3437-3439, 1994).

Regarding claims 45, 50, 60 and 64-66, Leu et al. teach a method of determining the abundance of an environmental parameter in an environmental sample comprising the steps of:

a. providing a first plurality of environmental samples at least some of which samples contain the environmental parameter (page 166, fourth paragraph; Table 1, where the samples were obtained from different oil fields);

b. isolating a plurality of genomic DNAs from the environmental each of the samples provided in step a (page 167, second paragraph);

c. isolating a plurality of 16S rRNA gene segments from each plurality of genomic DNAs isolated in step b (page 167, paragraphs 3-5);

d. determining the abundance of each of said 16S rRNA gene segments in each plurality of 16S rRNA gene segments isolated in step c (page 168, paragraphs 4-7; page 169, paragraphs 1-3 and 5);

e. determining the abundance of the environmental parameter in each of the samples provided in step a (page 171, fifth paragraph, where the presence of Desulfotomaculum genus was detected in original samples);

f. correlating the abundance of each 16S rRNA gene segment determined in step d with the abundance of the environmental parameter determined in step e (page 171, fifth paragraph; page 172, first paragraph).

Leu et al. do not specifically teach the steps g-k. However, they specifically suggest performing such steps (page 172, paragraphs 3 and 4):

"To understand the role SRB play in natural oil field environments, the comparative analysis of cloned 16S rDNA sequences should be used to characterize additional oil field samples without prior cultivation. Subsequently, SRB rDNA sequences retrieved from environmental samples by cloned sequencing could also be used for designing group- or species-specific hybridization probes to identify specific SRB, and also to determine their abundance and distribution. Recently, phylogenetic analysis has been successfully used to assess the divergence of 16S rRNA sequences from SRB in a sandy marine sediment and the developed hybridization probes have been able to evaluate efficiently the 16S rRNA of phylogenetically defined SRB group [19].

The present study is the first application of cloned 16S rDNA sequence analysis to examine the SRB cultures from oil field environments, and also to identify thermophilic sulfate-reducing microorganisms in cultures from different oil field samples in a range of locations. Phylogenetic analysis revealed that the thermophilic sulfate reducers, at least *Desulfotomaculum*-related species, may be common and widespread over oil fields and play an important role in the production of sulfide. Further exploration with a *Desulfotomaculum* group-specific probe in oil field samples will enable the confirmation and localization of *Desulfotomaculum* species. In addition to thermophilic

SRB, the thermophilic, non-sulfatereducing bacteria discovered in this study may also have an important ecological role, either directly or alongside SRB, in hydrocarbon reservoir souring."

Therefore, Leu et al. specifically suggest analysis of 16S rRNA sequences of bacterial populations obtained from oil fields, determining the most common and populous bacterial species and using probes based on their rRNA sequences to analyze samples from different oil fields. The expectation of success for this approach is provided by Devereux et al. who determined sequence diversity of bacteria from marine sediments without enrichment protocols and determined 16S rRNA sequences to be used for the detection of the different species (page 3437-3438).

Thus it would have been prima facie obvious to one of ordinary skill in the art at the time of the invention to have used the suggested method of Leu et al. and Devereux et al. to obtain the abundance of bacteria in oil fields. The motivation to do so is provided by Leu et al., who state (page 165, first paragraph and page 172, first paragraph):

"Sulfate-reducing bacteria (SRB) are strictly anaerobic microorganisms responsible for the terminal mineralization of organic material in anoxic environments. The growth of SRB in oil-bearing reservoirs has been shown to be responsible for oil formation souring [1,2]. So far, the mechanisms of the process are not fully understood, and consequently reservoir souring associated with sulfide-producing microorganisms is still seen as a major research topic."

"Therefore, by integrating many studies on thermophilic sulfate reducers, it can be postulated that both *Archaeoglobus* species and *Desulfotomaculum* species may play important roles in the biogenic production of H_2S in hot oil field environments, with hyperthermophilic *Archaeoglobus* species more likely being the major contributor in environments with temperatures above 65°C, and *Desulfotomaculum* species being responsible for sulfide production in environments with temperatures between 45°C and 70°C."

13. No claims are allowed.

Conclusion

14. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TERESA E. STRZELECKA whose telephone number is (571)272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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November 30, 2009